Appl. No. 10/539,662

Amdt. Dated January 24, 2008

Reply to Office Action of November 28, 2007

Attorney Docket No. 83363.0012 Customer No. 26021

<u>REMARKS</u>

This application has been carefully reviewed in light of the Office Action dated

November 28, 2007. Claims 1-8 remain in this application. Claims 1 and 8 are the

independent Claims. It is believed that no new matter is involved in the amendments or

arguments presented herein. Reconsideration and entrance of the amendment in the

application are respectfully requested.

Art-Based Rejections

Claims 1-4 and 6-8 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No.

6,013,084 (Ken) in view of U.S. Patent No. 6,468,266 (Bashiri) and U.S. Patent

Publication No. 2004/0002732 (Teoh); Claim 5 was rejected as obvious over Ken in

view of Bashiri and Teoh and U.S. Patent Publication No. 2004/0034363 (Wilson).

Applicant respectfully traverses the rejections and submits that the claims herein

are patentable in light of the arguments below.

The Ken Reference

Ken is directed to a vaso-occlusive coil 102 and stretch-resisting member 108. A

hook 199 is fixed to coil 191 (See Ken; FIG. 10).

The Bashiri Reference

Bashiri is directed to an assembly for placing an implant in the human body be

electrically isolating the implant 114 from a core wire 110 and electrolytically severable

joint 112. A hook 138 is fixed to implant 120 (See Bashiri; Abstract and FIG. 3).

The Teoh Reference

Teoh is directed to a stretch-resisting member 108 containing links that may be in

a twisting form. A closed loop 176 is directly connected to a plurality of twisted links.

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Ball 182 is directly attached to one of the twisted links by a sealed junction 180 (See

Teoh; FIG. 2C, 2D and Paragraphs [0055]-[0056]).

The Wilson Reference

Wilson is directed to a vaso-occlusive coil 10 reinforced with a stretch resistant

member 18 to improve safety during retraction of the coil. A loop 34 is attached to the

coil 12 (See Wilson; Abstract, FIG. 4 and Paragraph [0030]).

The Claims are Patentable Over the Cited References

The present application is generally directed to an indwelling implant for

embolization.

As defined by independent Claim 1, an indwelling implant for embolization

includes a coil composed of a metal and a substantially semi-spherical rounded head

portion at the distal end of the coil. A single closed loop is provided inside the coil from

the head portion toward the proximal end portion of the coil. An axial extension

controlling member composed of at least one wire material which is thinner than the

metal wire material forming the loop is provided inside the coil by extending the member

in the coil axial direction of the coil and fixing both ends thereof directly or indirectly to

the proximal end portion after the member passed through the loop. The single closed

loop is directly fixed to the rounded head portion and directly coupled to the axial

extension controlling member.

The applied references do not disclose or suggest the features of the present

invention as defined by independent Claim 1. In particular, the applied references do

not disclose or suggest, "the [axial extension controlling] member passed through said

loop," and, "the single closed loop is directly fixed to the rounded head portion and

directly coupled to the axial extension controlling member," as required by independent

Claim 1.

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Ken discloses a hook 199 that is directly fixed to coil 191, but is not fixed to a head portion (See Ken; FIG. 10).

On page 3 of the Office Action, Teoh is asserted to teach an element 108 that is a single closed loop which is directly fixed to a rounded head portion 107. Applicant respectfully points out that while Teoh discloses a loop 108 that is directly fixed to a head portion at a distal end portion thereof (*See, Teoh, Fig. 1*), the loop disclosed by Teoh is an axial extension controlling member as shown, for example, in Teoh, Fig. 2a. Therefore Teoh does not disclose or teach "an axial extension controlling member" and "a loop", as required by independent Claim 1 of the present invention.

Moreover, Applicant respectfully submits that the assertion that stretch-resisting member 108 is a single closed loop disregards both the claimed invention and references when considered as a whole (See M.P.E.P. § 2141). Even when interpreted broadly, the claims require the distinct components of a single closed loop, an axial extension controlling member and a rounded head portion. In particular, the axial extension controlling member is not the same as the single closed loop since the controlling member is coupled and passed through the loop.

Teoh teaches, at best, that stretch-resisting member 108 has a loop. However, any loop disclosed provided within stretch-resisting member 108 is clearly not the distinctly claimed single closed loop fixed to both the rounded head portion and coupled to the axial extension controlling member since the loop is integral to the stretch-resisting member 108. Furthermore, the stretch-resisting member 108 cannot be both the axial extension controlling member and the loop since the extension member must be passed through the loop. Therefore, the stretch-resisting member 108 cannot be construed to be the single closed loop that is coupled and passed through the axial extension controlling member of the present invention. Thus, Teoh merely teaches a stretch-resisting member 108 that is directly attached to a distal cap 107. In sum, only

two out of the three required claim elements are shown in Teoh and the stretch-resisting member 108 has been misconstrued to represent a single closed loop.

In contrast, the present invention requires that the axial extension controlling member to pass through a single closed loop and for the single closed loop to be directly fixed to the rounded head portion and directly coupled to the axial extension controlling member. In this manner, an axial extension controlling member can be inserted and pulled through the loop to thereby fix the axial extension controlling member to the metal coil. As a result, the present invention can advantageously prevent the annealing-induced decrease in strength of the welded portion that occurs when the axial extension controlling member is directly welded to the distal end portion of the metal coil. Thus, sufficient strength is provided to the stretching preventing mechanism (See Specification; Page 17, lines 14-27).

As stated on page 3, line 26 to page 4, line 5 of the present specification,

when the extension controlling member was welded to the coil, the strength of the extension controlling member in the welded zone was greatly reduced by annealing. Therefore, the cross sectional area of the extension controlling member had to be sufficiently increased in order to obtain a strength necessary for the extension controlling member. The resultant problem was that flexibility of the indwelling implant for embolization was lost.

As pointed out above, the extension controlling member (loop 108) of Teoh is directly fixed to a head portion. Accordingly, unless the diameter of the fixed extension controlling member is enlarged, the problem of the strength cannot be resolved. But, if the diameter of the loop 108 is enlarged, the softness is damaged. Accordingly the above-mentioned problem cannot be resolved by Teoh. Because Teoh welds the stretch-resisting member 108 directly to the distal cap 107 in the same disadvantageous manner as described by Applicant, so as to decrease the strength of the welded portion.

Teoh teaches against Applicant's stated purpose and thus provides no motivation or suggestion to combine Teoh with the applied references.

As also mentioned above, for the purpose of demonstrating the effect of the present invention, it is necessary that the loop be directly fixed to a head portion and the loop be connected to an extension controlling member which is thinner than the loop.

Accordingly, even applying the structure of Teoh to Ken, the structure of the present invention cannot be obtained. According to the present invention, what is fixed to a head portion is only a loop which is molded thicker than an extension controlling member. The extension controlling member passes through the loop and it is not required to be heated by welding in order to fix. Accordingly as shown in Fig. 1, it becomes possible to make the extension controlling member provided in an indwelling implant for a long time thinner and sufficient softness can be maintained.

On the other hand, when the distal end portion of the coil is made such as 199 of Fig. 10 of Ken, 136 of Fig. 3 of Bashiri, or 150 of Fig. 2A of Teoh, although the purpose is to prevent the outer side coil from extending, the inner side thin coil portion may be extended or cut in advance because the extension controlling member is fixed through the coil thinner than this. As a result, the extension controlling member cannot present the outer side large coil from extending efficiently.

The ancillary references do not remedy the deficiencies of Ken and Teoh. Wilson teaches a loop 34 which is directly attached to the coil 12 and not to distal end 14 (See Wilson; Abstract, FIG. 4 and Paragraph [0030]).

Since the applied references fail to disclose, teach or suggest the above features recited in independent Claim 1, those references cannot be said to anticipate nor render obvious the invention which is the subject matter of that claim.

Accordingly, independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

Applicant respectfully submits that independent Claim 8 is allowable for at least the same reasons as those discussed above with respect to independent Claim 1.

The remaining claims depend either directly or indirectly from independent Claims 1 and 8 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance.

Conclusion

Applicant believes the foregoing amendments comply with requirements of form and thus may be admitted under 37 C.F.R. § 1.116(b). Alternatively, if these amendments are deemed to touch the merits, admission is requested under 37 C.F.R. § 1.116(c). In this connection, these amendments were not earlier presented because they are in response to the matters pointed out for the first time in the Final Office Action.

Lastly, admission is requested under 37 C.F.R. § 1.116(b) as presenting rejected claims in better form for consideration on appeal.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

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If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,

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